PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

Approved for use through 10/31/2002. OMB 0851-0031

B. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are respect to respond to a collection of information unless it contains a united OAP Substitute for form 1449A/PTO Complete if Known 09/757,688 **Application Number** INFORMATION DISCLOSURE January 11, 2001 Filing Date STATEMENT BY APPLICANT First Named Inventor Wolfgang HEIL et al. **Group Art Unit** 1615 (use as many sheets as necessary) **Examiner Name** L.S. Channavajjala of Attorney Docket Number **PLOVIN-2A**

MAR 0 7 2005

	٠,		U.S. P	ATENT DOCUMENTS	
		U.S. Patent Docur	ment		
Examiner	/		Kind Code ²	Name of Patentee or Applicant	Date of Publication of Cited Document
tnikets*	Cite No."	Number	(# known)	of Cited Document	MM-DD-YYYY
W		5,534,270		De Castro	7/9/1996

	FOREIGN PATENT DOCUMENTS											
S			Foreign Patent Docu			Date of Publication of	Pages, Columns, Lines, Where Relevant					
Examiner Initials*	Cite No.1	Office ³	Number ⁴	Kind Code ^s (# known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear	T ⁶				
		CA	2 188 907			4/29/1997						

caminer nitials	Cite No.1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-lasue number(s), publisher, city and/or country where published.	т,					
R	//	International Preliminary Examination Report dated 11/29/2001						
	-	Remington 2, Farmacia, 17 edicion, Editorial Medica, Panamericana						
A.	-	S. Budavari, et al., "The Merck Index", Merck & Co., Inc., Whitehouse Station, NJ (1996)						
		P. Giunchedi et al., "Spray-drying as a preparation method of microparticulate drug delivery systems: an overview, "STP Pharma Sciences 5 (4) 276-290 (1995)						
		J. Broadhead, et al., "The Spray Drying of Pharmactuticals", Drug Development and Industrial Pharmacy, 18 (11&12), pgs. 1169-1206 (1992)						
	-	P. Muhn et al., "Drospirenone: A Novel Progestogen with Antimineralocorticoid and Antiandrogenic Activity", Pharmacological Characterization IN animal Models (1995), pgs. 99-110						
		"Letters to the Editor", Gynecol Endocrinol 200, 14:476-478						
		J.W. Tack, "Invitation To the Doctoral Candidates' Colloquium", dated 2-5-1998						
		N. Sattar, et al., "Reproductive Endocrinology Lipoprotein Subfraction Changes in Normal Pregnancy: Threshold Effect of Plasma Triglyceride on Appearance of Small, Dense Low Density Lipoprotein ¹ , "The Journal of Clinical Endocrinology & Metabolism Vol. 82, No. 8 2483-2491 (1997)						
	-	Letter dated 7-7-2004 re: CHLE Patent Appln. No. 2353-20000 filed 8-30-2000						
	-	Opposition to a European Patent Office, Patent No. 1 214 076						
	y	CA 136:172763, "Method for preparing an oral formulation containing acid-sensitive drugs, Hsiao, et al.						
CA 129:235662, "Stabilization of acid sensitive benzimidaxoles with amino acid/cyclodextrin combinations", Klokkers, et al.								

EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{**}Unique citation designation number. ** See attached Kinds of U.S. Patent Documents. ** Emer Office that issued the document, by the two-letter code (WIPO Standard ST.3). ** For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ** Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 15 if possible. ** Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box -> +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002, OMB 0851-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of

Complete If Known								
Application Number	09/757,688							
Filing Date	January 11, 2001							
First Named Inventor	Wolfgang HEIL et al.							
Group Art Unit	1615							
Examiner Name	L.S. Channavajjala							
Attorney Docket Number	PLOVIN-2A							

	NON PATENT LITERATURE DOCUMENTS
Examiner Initials * Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. T ²
	L. Lachman et al., "The Theory and Practice of Industrial Pharmacy", Lea & Febiger, Phila. (1970) pgs. 104-108
	English-language translation of K. H. Bauer et al. article 1993
	English-language translation of W.A. Ritschel, et al., "The Tablet – Manual on Development, Production and Quality Control", Editio Cantor Verlag Aulendorf
R	English-language translation of P. H. List, et al. article, "Pharmacology –A Testbook for Pharmacists", Wissenschaftliche Verlagsgesellschaft mbH Stuttgart (1980)
R	English-language translation of R. Voigt et al. article, "Pharmaceutical Technology – For Study and Professional Reference", Ullstein Mosby 1993
Examiner Signature	L. Channarayal Date Considered 7/20/25

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Urique citation designation number, ² See attached Kinds of U.S. Patent Documents, ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

	r on of tot ea		o to be 20th Suite:	U.S. Patent and Tradema a-red to respond to a corection of infe	م لحقیس	Kası il containe	arm.of	dougo um	mber
ompour!	B (C) (D (I) (14500F10		Complete if Known					
INFC	SMA	TION DISCLO	SHPE	Application Number	+	7,688			
		NT BY APPLI	,_,	Filing Date		ary 11, 20	21		
VIA		MI BI AFFE	CAN	First Named Inventor Group Art Und		ang HEIL			
	(use 35)	nany sheets as necess	sary)	Examiner Name	1615				
Sneet	 -	1 of	1	Attorney Docket Number		ning Hui 'IN-2A			
-				TENT DOCUMENTS	1,500	114-57			
•		U S Patent Dec		FIEWI DOCUMENTS		,			
aner 140 5	Cite N 2.	Number	Kind Code ² (# known)	Name of Patenthe or Application of Cited Documen	am	Damori	מספיים. מעי 10-ה פי	of Cased Do	cumstr
X		6,787,531		Hilman et al.	-			2004	
									
-									
			- - 						
						_			
									
	Can N. I	Foreign Patent Do	Kand Coda*	PATENT DOCUMENTS Name of Patentine or Applicant of	Cred D	islication of	V. CEPE	Huttina, Lines Rejouant or Rejouant	
	Cde N ; '	Foreign Patent Do	JUSTINA S		Cred D		V.GETE Po=L_GET	Repugn	1
	Cae N , '		Kand Coda*	Name of Patenties or Applicant of	Cred D	ocument	V.GETE Po=L_GET	Retovent or Retovent	
	Cde N,	Office' Number	Kand Coda*	Name of Patenties or Applicant of	Cred D	ocument	V.GETE Po=L_GET	Retovent or Retovent	
	Cae N, '	Office' Number	Kand Coda* (d Mown)	Name of Patenties or Applicant of Cree Document	Cred E	ocument	V.GETE Po=L_GET	Retovent or Retovent	
runda.		Office' Number	KARD COGGS (# ANOWA)	Name of Patentiae or Applicant of Cited Document	Cred E	D-YYYY	Post gas	Regulati FOR Relevant S Appear	
±gumuni nu kai≥,		former sous Shubosmui	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MAN-O NTS PERDENATE PRESENT	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
-Smatul		former sous Shubosmui	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Cited Document	Cred E MAN-O NTS PERDENATE PRESENT	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
-Smatul		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MAN-O NTS PERDENATE PRESENT	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
±gumuni nu kai≥,		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MRS-D NTS ppropriate) publisher.	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
±gumuni nu kai≥,		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MRS-D NTS ppropriate) publisher.	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
runda.		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MRS-D NTS ppropriate) publisher.	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
±gumuni nu kai≥,		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MRS-D NTS ppropriate) publisher.	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
Adminer states and sta		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MRS-D NTS ppropriate) publisher.	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r
runda.		Office, white a final series of the series o	KARD CODE* (# INTOWN) CON PATENT TO US CAPITAL LE 081310g etc.), date	Name of Patentiae or Applicant of Citied Document LITERATURE DOCUME TTERS), tips of the structs (which applicat), volume-state number(s).	Cred E MRS-D NTS ppropriate) publisher.	Age of the fac	P. and P.	Верчен от Ремочин в Аррият педазине, го ризирно	r

Please type a p

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO Complete if Known **Application Number** 09/757,688 INFORMATION DISCLOSURE Filing Date January 11, 2001 STATEMENT BY APPLICANT First Named Inventor Wolfgang HEIL et al. 1615 **Group Art Unit** (use as many sheets as necessary) **Examiner Name** L.S. Channavajjala Sheet PLOVIN-2A **Attorney Docket Number** Higher Copper to U.S. PATENT DOCUMENTS U.S. Patent Document Name of Patentee or Applicant of Cited Document Examiner Date of Publication of Cited Document MM-DD-YYYY Initials * Cite No.1 (if known) Number

		î»		FOREIGI	N PATENT DOCUMENTS	Mar Sea Se	Fig. Begit in Market	
Examiner Initials*	Cite No.1	Office ³	Foreign Patent D		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	™
				<u> </u>				

1.7 2.8	ė.	NON PATENT LITERATURE DOCUMENTS	
Examiner Initiats *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т²
Contract of the State of the St		ANDA Notification by Barr Laboratories (14 pgs.)	
			-
	-		
_			
			
Examin Signatu		L. Channavajjale considered 1/20/00	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique diation designation number. ² See attached Kinds of U.S. Patent Documents. ² Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a chack mark here if English tanguage Translation is attached.

Please type a plus sign (+) inside this box

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are req

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

Complete if Known **Application Number** 09/757,688 Filing Date January 11, 2001 First Named Inventor Wolfgang HEIL et al. **Group Art Unit** 1615 L.S. Channavajjala **Examiner Name** PLOVIN-2A **Attorney Docket Number**

			U.S. PAT	ENT DOCUMENTS	
		U.S. Patent Document			
xaminer Initial	Cite No.1		d Code ^z known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
48		2,243,887		Serini et al.	6/3/1941
1		5,382,434		de Haan et al.	1/17/1995
		4,900,734		Maxson et al.	2/13/1990
		4,826,831		Plunkett et al.	5/2/1989
II		4,196,188		Besins	4/1/1980
1		4,927,816		Ester	5/22/1990

		•		FOREIGI	N PATENT DOCUMENTS			
Examiner			Foreign Patent Doc		Name of Patentee or Applicant of	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	ŀ
Initials*	Cite No.'	Ottice,	Number ⁴	(if known)	Cited Document	MM-DD-YYYY	Figures Appear	- 1

		NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-Issue number(s), publisher, city and/or country where published.							
#	EP·0 461 290 12/18/1991 (abstract) attached								
	Chaumeil, J.C., "Micronization: A Method of Improving the Bioavailability of Poorly Soluble Drugs", Meth. Find. Exp. Clin. Pharmacol., 1998, pgs. 211-215.								
	McInnes, G.T., et al., "Effect of micronization on the bioavailability and pharmacologic activity of spironolactone", Journal of Clinical Pharmacology, 1982; 22:410-417.								
	1	DeVilliers, Melgardt M., "Influence of cohesive properties of micronized drug powders on particle size analysis", Journal of Pharm. & Biomedical Analysis, Vol. 13, No. 3, pgs. 191-198, (1995).							
/	/	Fotherby, K., "Bioavailability of Orally Administered Sex Steroids Used in Oral, Contraception and Hormone Replacement Therapy", Elsevier Science, Inc., 1996; pgs. 59-69.							
A		English-language description from Chile attorney of Opposition in Chile to Chile Application No. 2353-2000							
Examiner Signature		L. Channavayale Date considered 5/23/05							

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

¹ Unique distion designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English tanguage Translation is attached.

PTO/SB/08A (08-00) Approved for use through 10/31/2002. OMB 0651-0031

U	nder the Pap	erwork Rec	duction A	ct of 1995, no	persons are re	equired to respond to a collection of info				ber.		
Substitute	o for form 1	449A/PTC)				Complete if Known					
						Application Number	09/75	7,688				
INFO	RMAT	LION	DIS	CLOSI	JRE	Filing Date	Janua	ry 11, 200	01			
STAT	TEME	NT B	Y AF	PLICA	NT	First Named Inventor	Wolfg	ang HEIL	et al.			
_		_				Group Art Unit	1615					
	(use as n	nany she	ets as	necessary)	<u> </u>	Examiner Name	L.S. C	hannavaj	jala			
Sheet	1 of 1				1	Attorney Docket Number	PLOV	PLOVIN-2A				
			,		U.S. P	ATENT DOCUMENTS						
_			U.S. Pa	itent Docume	nt							
Examiner Initials *	Cite No.1		Numbe	er	Kind Code ² (If known)	Name of Patentee or Applic of Cited Document	Name of Patentee or Applicant Date of locument			ument		
					FOREIGI	N PATENT DOCUMENTS						
	Foreign Patent Document						Date of P	ublication of	Pages, Columns, Lines, Where Relevant			
Examiner Initials*	Cite No.1	Office ³	N	umber ⁴	Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Cited D	D-YYYY	Passages or Relevant Figures Appear	T [®]		

		NON PATENT LITERATURE DOCUMENTS	
Examiner thitials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
R		Y. Pramar et al. "Preformulation Studies of Spironolactone: Effect of pH, Two Buffer Species, Ionic Strength, and Temperature on Stability", Journal of Pharm. Sciences, Vol. 80, No. 6, (1991), pgs. 551-553	
R		E. R. Garrett et al., "Prediction of Stability in Pharmaceutical Preparations XVI: Kinetics of Hydrolysis of Canrenone and Lactonization of Canrenoic Acid", Vol. 60, No. 12, (1971), pgs. 1801-1809	
·			
-			
-			
Examin Signatu	_	L. Channavayale Date Considered 5/23/05	

EXAMINER: tritial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-latter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.